Office of
Agricultural
Biotechnology

Minutes

Agricultural Biotechnology Research Advisory Committee

March 23-24, 1988

Document No. 88-01

U.S. DEPARTMENT OF AGRICULTURE
AGRICULTURAL BIOTECHNOLOGY RESEARCH ADVISORY COMMITTEE
MINUTES OF MEETING

March 23-24, 1988

The first meeting of the Agricultural Biotechnology Research Advisory Committee (ABRAC) was held March 23-24, 1988 at the U.S. Department of Agriculture's Jefferson Auditorium, Washington, D.C. The meeting was open to the public, announced in the Federal Register and was attended by approximately 35 visitors representing various agencies, media, and the public.

Welcome

Dr. Orville G. Bentley, Assistant Secretary for Science and Education, opened the meeting by welcoming all in attendance and expressing the Department's appreciation for the Committee's willingness to serve.

Charge to the Committee

Dr. Bentley stated that the ABRAC will have a critical role in helping to develop and implement procedural and scientific goals of the coordinated framework for the biosafety review of biotechnology research in agriculture. He stated that the aim is to reduce the risk of possible short- and long-term hazards to society and to the environment and to assure that the potential benefits of biotechnology are not lost to future generations. He stated that ABRAC will help to insure that prudent, well-designed research protocols are available to all researchers in the form of a set of research guidelines and a roadmap to clarify the responsibility of scientists, research institutions, Institutional Biosafety Committees (IBCs), and the Federal government. He said research institutions and scientists need to develop an understanding and a procedural pathway for initiating research and field testing organisms modified by biotechnology. This will help to assure that scientists have a firm scientific base and formal procedures to use in meeting their responsibilities regarding potential safety concerns when genetically engineered organisms are tested initially outside the laboratory.

Introduction of ABRAC Chair, Committee Members and Alternates

Dr. Bentley introduced Dr. Bennie Osburn, the Chair of ABRAC, Professor of Pathology and Associate Dean for Research at the School of Veterinary Medicine at the University of California, Davis.

Dr. Osburn called the meeting to order and stated that this first meeting would be primarily informational and would include initial discussions of Committee operations and procedures. He stated that the charge presented to ABRAC by Dr. Bentley was a great challenge, and that the USDA Office of Agricultural Biotechnology, the National

Biological Impact Assessment Program (NBIAP), and the National Association of State Universities and Land-Grant Colleges (NASULGC), would be important resources to the committee.

Dr. Osburn introduced the 13 committee members and the 13 alternates. (Names of those unable to attend are preceded by an asterisk.)

Committee Members

Dr. Rodney Bothast, Vice-Chair, Northern Regional Research Laboratory, Peoria, IL;
Dr. Nicholas Frey, Pioneer Hi-Bred International, Inc., Johnston, IA;
*Dr. John Gorham, Washington State University, Pullman, WA;
Dr. Fred Gould, North Carolina State University, Raleigh, NC;
Dr. Harold Hafs, Merck, Sharp & Dome Research Laboratories, Rahway, NJ;

Ms. Anne K. Hollander, Conservation Foundation, Washington, DC;
Dr. John Kemp, New Mexico State University, Las Cruces, NM;
Dr. Edward Korwek, Hogan and Hartson, Washington, DC;
Dr. Linda Phaire-Washington, Tuskegee University, Tuskegee, AL;
Dr. A. Ann Sorensen, American Farm Bureau Federation, Park Ridge, IL;
Dr. Sue Tolin, Virginia Polytechnic Institute and State University, Blacksburg, VA;
Dr. Frank Whitmore, Ohio Agricultural Research and Development Center, Wooster, OH.

Alternates

*Dr. Peter Carlson, Crop Genetics International, Dorsey, MD;
*Dr. Arnold Demain, Massachusetts Institute of Technology, Cambridge, MA;
Mr. Jeffrey Gibbs, Mackler, Cooper, and Gibbs, Washington, DC;
Dr. George Hill, Meharry Medical College, Nashville, TN;
Dr. Ariel Hollinshead, George Washington University, Washington, DC;
Dr. A. David Kline, Iowa State University, Ames, IA;
Dr. Shain-dow Kung, University of Maryland, College Park, MD;
Dr. Steven Lindow, University of California, Berkeley, CA;
Dr. Lois Miller, University of Georgia, Athens, GA;
Dr. Ronald Sederoff, North Carolina State University, Raleigh, NC;
Dr. Anne Vidaver, University of Nebraska, Lincoln, NE;
Dr. Thomas Wagner, Ohio University, Athens, OH;
Dr. Richard Witter, Michigan State University, East Lansing, MI.
*Unable to attend.

Dr. Alvin Young, Director of the Office of Agricultural Biotechnology (OAB) and Executive Secretary of the ABRAC, introduced his staff. It included:

Dr. Daniel Jones, Deputy Director; Dr. Michael Olexa, Policy Adviser; Ms. Marti Asner, Public Affairs Specialist; Ms. Eva Russnak, Administrative Coordinator; and Ms. Elsie Brown, Secretary to the Director and OAB. Joining OAB in mid-April will be Dr. David MacKenzie, Louisiana State University, and Dr. Althaea Langston, APHIS.

Other representatives and guest speakers from the U.S. Department of Agriculture included:
Honorable Peter C. Myers, Deputy Secretary. Mr. Myers addressed the Committee briefly, then speakers from several agencies within USDA described biotechnology programs and procedures within their agencies. USDA speakers included:
Dr. Jerome P. Miksche, Agricultural Research Service, National Program Leader, Plant Physiology;
Dr. Stanley L. Krugman, Forest Service, Director, Timber Management Research;
Dr. John Patrick Jordan, Administrator, Cooperative State Research Service;
Dr. John E. Lee, Administrator, Economic Research Service;
Terry L. Medley, Esq., Director, Biotechnology and Environmental Coordination Staff, Animal and Plant Health Inspection Service;
Dr. Lester M. Crawford, Administrator, Food Safety and Inspection Service.
Dr. Kenneth A. Gilles, Assistant Secretary, Marketing and Inspection Services, discussed the position and policies of the regulatory agencies within USDA.

Additional Questions and Comments: Dr. Jordan was asked how many proposals potentially could come for ABRAC review in the next year or so. Dr. Jordan estimated a substantial number, perhaps 50 to 100 projects a year, perhaps fewer depending on field test guidelines provided by ABRAC. Dr. Osburn asked Dr. Jordan if the agricultural research community understands how ABRAC is going to participate; if not, how will the information get out? Dr. Jordan said there is a need for communication and dialogue between USDA and agricultural researchers. Dr. Young said that communication is especially critical now because there are no guidelines and that one of ABRAC's tasks would be developing and publishing guidelines. Dr. Young said institutional biosafety issues must be identified as well as how institutions will interface with OAB and ABRAC. Dr. Jordan said that because of the number of issues to be resolved, at least two more ABRAC meetings would be needed this year. In regard to NBIAP, Dr. Young asked if the university system has plans for sites allowing both contained and field research without having to build special facilities? Dr. Jordan said this had been addressed in a letter to Mr. Whitten.

Ms. Jane Rissler, National Wildlife Federation, asked if ABRAC deliberations would be open; if only USDA-sponsored research will be reviewed; if research proposals from industry will be reviewed by ABRAC; and what is the scope of products to be reviewed by ABRAC? Dr. Young replied that ABRAC meetings will be open except for those at which special considerations such as confidential business information, etc., apply. Meetings will be announced in the Federal Register, with an open session in each meeting. The ABRAC may consider biotechnology research other than recombinant DNA research. ABRAC is expected to focus primarily on USDA-funded research; it may consider other research if it is asked to do so. Research Guidelines in preparation will invite the private sector to use the system on a voluntary basis.

APHIS and other regulatory agencies will regulate products of biotechnology much as they have other regulated products since ABRAC has no regulatory authority.

Purpose and Role of the Committee

Dr. Young, presented the purpose and role of the Committee as follows:

(1) Reviewing proposed USDA-funded research projects involving environmental release of genetically engineered organisms that are not covered by research guidelines.

(2) Evaluating the adequacy of draft proposals to be used by the Department in the preparation of research Environmental Assessments (EAs).

(3) Providing recommendations on protocols and research guidelines.

(4) Providing advice to other federal and state agencies on agriculture-related research projects.

(5) Providing information to and maintaining capability of the Institutional Biosafety Committees (IBCs).

Organization

Dr. Young described the organization of the Committee as follows:

ABRAC members are appointed by the Secretary of Agriculture. The Committee will have a Chair, a Vice Chair, and an Executive Secretary, who is the Director of OAB. Meetings will not be conducted in the absence of the Executive Secretary or his or her designee.

The Committee, including Chair and Vice Chair, will consist of 13 voting members, of whom no more than four will be Federal employees. The alternate for a member will attend meetings in the member's place when the member is unable to attend.

Subject matter expertise of ABRAC members and alternates will be in the following areas: recombinant DNA research on plants, animals and microbes; ecology; epidemiology and environmental science; agricultural production practices; biological containment; biological field release; applicable laws and regulations; standards of conduct and practice; public attitudes; public health; occupational health and ethics.

Equal opportunity practices according to USDA policies will be followed in all appointments to the ABRAC. Additional individuals representing Federal and state agencies shall be non-voting participants and may be used to provide advice and expertise. Consultants may be called upon for advice on an ad-hoc basis.

Concerns and Challenges

Dr. Young raised a number of concerns and challenges related to the ABRAC and its mission. Among these were:

1) a need to develop a working definition of biotechnology. How far should this go beyond recombinant DNA?

2) the role of the Cooperative Extension Service; there may be a need to address the policy issues regarding promotion of technology transfer;

3) the June 1986 Coordinated Framework for Biotechnology defined USDA research and regulatory policy; APHIS' and FSIS' regulatory programs are in place. Science and Education's research guidelines have not been formalized, and need to come before ABRAC very soon; and

4) the OAB is responsibile for coordination among the regulatory and research areas of USDA, but it looks to ABRAC to assure the biosafety of agricultural research.

Procedures

Dr. Young outlined procedures for USDA-funded research including activities of the principal investigator and the IBC, submission of applications to regulatory agencies, the preparation of EA's, and OAB and ABRAC involvement.

Anne Hollander asked what percentage of USDA-funded research falls into the two categories--those examined by APHIS and those going to ABRAC. Dr. Young replied that the relative percentages are not known, however no proposal should require two EAs. If APHIS prepares the EA it will look at biosafety issues. If APHIS is not involved in a federally-funded project, ABRAC has the responsibility of looking at the project and providing an EA to the Assistant Secretary for Science and Education.

Dr. Hill asked how long an APHIS review for procedural safety will take. Mr. Medley said that APHIS has 120 days to complete their review; any involvement from OAB or ABRAC has to fit this mandatory review time.

Mr. Medley said that regulations do not distinguish between research, academic and private releases. The organism and activity/risk are reviewed for the decision as to whether an organism or product is regulated. The researcher has knowledge about the biology of the organisms and the constructs, and he or she is in the best position to determine whether or not a particular release triggers the regulations. The researcher bears the initial responsibility for determining whether a permit application must be filed and this would determine the time frame.

Dr. Miller of FDA asked how different agencies are going to handle the EA the principal investigator files. Dr. Young indicated that guidance would be given through presentations, a handbook, or research guidelines. If an application goes to APHIS, the principal investigator submits information about the biology of the organism and the constructs and APHIS prepares the EA.

Dr. Gould asked how agencies divide responsibility in cases dealing with both a plant and a toxic substance, such as Bacillus thuringiensis (Bt) toxin.

Mr. Medley answered that EPA is publishing proposed regulations to implement the policies listed in the June 1986 coordinated framework, one of which deals with plants. Currently under a memorandum of understanding between EPA and USDA, APHIS reviews submissions, gets input from states of destination, then sends their assessments to EPA. EPA reviews the APHIS assessment, and concurs or identifies additional issues. APHIS coordinates the process, which is completed within the 120 day period. On microorganisms where both EPA and USDA permits, are needed researchers submit identical data to EPA and APHIS which have coordinated their requirements. Reviews are independent but coordinated to minimize duplication and unnecessary delays.

Dr. Phaire-Washington asked about the need for site visits in conjunction with ABRAC's function. Dr. Young responded that the mechanism for this will have to be decided. He suggested that OAB, and the National Biological Impact Assessment Program (NBIAP), or the investigator could assist here.

National Environmental Policy Act

Mr. John Cohrssen of the Council on Environmental Quality (CEQ) discussed the National Environmental Policy Act (NEPA), which requires certain kinds of environmental documentation for all major Federal actions. Mr. Cohrssen said he hopes that the research guidelines will include categories of experiments that are exempt from USDA review. He cautioned ABRAC to be clear as to their policies with regard to NEPA, and specifically as to what decision is being made by a Federal official.

Dr. Henry Miller, FDA, asked for a recapitulation of the spectrum of products and investigators that will be affected by what are perceived as new requirements [the research guidelines], and a new level of bureaucracy [ABRAC and OAB]. Dr. Young responded that at this time the mechanism appears complex, and there is great concern about not wanting to put something in place that will impede research, however, ABRAC will be an excellent tool for assuring the public that agricultural research does not pose a safety problem. Its goal should be to make judgments as rapidly as possible, and have fewer types of proposals go to ABRAC. We must address the biosafety issue, but this should not be so difficult that it impedes research. Developing the scientific basis for exemptions from review would also be a possible role for ABRAC.

Mr. Cohrssen asked if any consideration had been given to what items would not fall under ABRAC review. Dr. Young said that OAB and ABRAC need to work on defining this area.

Administrative Matters
Mrs. Russnak of OAB stated that OAB is required to file an annual report to Congress on advisory committee activity and that the information provided would include the Committee's accomplishments, purposes, effectiveness, advice or recommendations for improvement, and expenditures. She also explained the procedures for reimbursement of travel expenses.

Recording of Minutes
Dr. Young stated that the proceedings are recorded and a transcript prepared by a commercial recording service. OAB summarizes the transcript into minutes, then submits these to the Chair with a copy of the transcript. The Chair reviews both documents, makes changes or comments, and returns the documents to OAB; then OAB prepares final minutes which are discussed at the next meeting, changes or corrections are made, and the minutes approved.

Recommendations Proposed by OAB for Committee Operational Matters
Dr. Young presented recommendations proposed by OAB for committee operational matters. A copy of these recommendations is attached as Appendix B.

1. Frequency of Meetings. The next three meetings will be in Washington, DC on June 23-24, 1988, September 22-23, 1988 and January 5-6, 1989. Meetings will be in the USDA Administration Building, Williamsburg Room (Room 104-A).

Meetings will be open unless there is a specific reason to have a closed session.

2. Development of Agendas. OAB will develop agendas for meetings in consultation with the ABRAC Chair. Members or alternates may recommend agenda items to the Chair. Notice of major actions on ABRAC's agenda will be published in the Federal Register at least 30 days before a meeting. Dr. Vidaver asked if others could submit suggested agenda items. Dr. Young said that if ABRAC members agree, this could be added.

Dr. Korwek asked if agenda items should be sent to the Chair or to the Executive Secretary. Dr. Young responded that either way is acceptable.

3. Announcement of Meetings. OAB will publish announcements of meetings in the Federal Register at least 30 days prior to each meeting. Shorter notice may be provided if reasons for the exception is made a part of the Federal Register notice.

4. Attendance and Participation by Alternates. If a member cannot attend a meeting, their alternate may attend in their place. Alternates may exercise voting privileges only when substituting for a

member. Alternates will receive reimbursement when substituting for a member, or if they are designated by the Chair as primary reviewer.

5. Pre-meeting Informational Materials. OAB will distribute premeeting informational materials to members and alternates.

6. Rules of Order. Rules of order are at the Chair's discretion.

7. Voting. Only members and alternates substituting for members may vote on issues before the Committee. The Executive Secretary will perform a quorum check at each meeting, and determine which alternates are entitled to vote at that meeting. The Executive Secretary or his/her designee is responsible for counting and recording votes. For each vote taken, the minutes will show the abstentions and number of votes for and against. If members request, the minutes will identify by name, votes and abstentions on a particular issue. The Committee must decide if it wants to operate on a simple majority basis. Dr. Hollinshead suggested the NIH procedure of including minority opinions in the minutes. The ABRAC agreed to include minority opinions.

8. Ad hoc Committees and Primary Reviewers. There was discussion about use of non-ABRAC members for reviews, the impact of the Federal Advisory Committee Act, and who is a member of ABRAC (members and alternates, or just members); these questions will need clarification.

9. Priority Order of Speaking. The Chair will determine the priority order of speaking on specific issues.

10. Conflicts of Interest and Appearances of Conflict. Dr. Young discussed conflict of interest. Dr. Young emphasized that Committee members and alternates are expected to use discretion in avoiding conflicts of interest and the appearances of conflict of interest in their committee activities. Dr. Hollander suggested it would be useful for ABRAC members to have written criteria so that members and the public will have the same standard and be aware of what the standard is. Dr. Young said this would be included, and Dr. Osburn indicated it might be worthwhile to have all members sign a statement at each meeting.

11. Recording of Minutes. This was covered earlier in the meeting and was reviewed briefly.

12. Preparation of Minutes. OAB will prepare final minutes to go to members of ABRAC and alternates. At the next meeting these minutes will be reviewed, amended as appropriate, and adopted.

13. Public Information. Ms. Asner of OAB explained the public affairs aspects affecting ABRAC, the two main areas being explaining USDA's policies on agricultural biotechnology to the public, industry, research communities and other groups; and helping academic and research institutions with public relations plans in advance of field release.

14. Confidential Business Information (CBI). Dr. Jones of OAB gave a brief status report on the Confidential Business Information (CBI) proposed rule for OAB and ABRAC. He said it is currently being reviewed by the Office of Management and Budget.

Mr. Gibbs asked how CBI would be handled before the proposed rule is final. Dr. Jones replied that if CBI comes to ABRAC, its security could be protected by the use of commitment and receipt forms. The USDA General Counsel, however, encourages the promulgation of a final rule for CBI procedures.

Dr. Sederoff asked if an individual or a private institution can request confidentiality on something going to ABRAC. Dr. Jones said they can request that certain information be kept confidential, but if it relates to safety, there may be negotiation with the submitter on what should remain confidential. Some federal statutes are more specific than others about the tradeoff between public safety information and private confidential information. Dr. Jones thought the determination would be made on the basis of discussions with the submitter, and in the end may be a matter of judgment.

15. Adjournment Authorities. Ordinarily the Chair will adjourn meetings. If the chair is a non-federal employee, as in the present case, the Executive Secretary shall have the authority and is required to adjourn a meeting under circumstances where he or she considers adjournment to be in the public interest.

Comments made on the OAB procedural recommendations will be included in a rewrite of committee operational matters, which will be circulated to the committee prior to the next meeting.

Preview of Upcoming Issues--Dr. Jones summarized several issues that may affect ABRAC discussions and activities. They were: pending NIH actions; USDA S&E guidelines for agricultural research; and the relationship between the Federal government and Institutional Biosafety Committees.

Pending NIH actions--Dr. Jones indicated that in August of 1987 NIH published a proposal to add two new appendices to the NIH Guidelines, one on greenhouse guidelines containing information on physical and biological containment for recombinant DNA research involving plants, and the other on physical and biological containment for recombinant DNA research involving animals. Both appendices were proposed in response to requests from USDA to expand NIH Guidelines to cover certain kinds of research that are important to agriculture. NIH agreed to add these appendices, which still relate to contained research. Recent discussions with the NIH Office of Recombinant DNA Activities (ORDA) indicate that they are close to finalizing the two appendices. However, an EA may need to be prepared and NIH has requested assistance from USDA.

The development of USDA S&E Guidelines for Agricultural Research Dr. Jones indicated that the development of research guidelines is a major responsibility both for USDA and ABRAC. USDA intends that the current approach will result in research guidelines that will be of assistance to the agricultural research community. The current plan is to publish in the Federal Register a notice of the guidelines as they are developed.

As a complement to the guidelines, USDA intends to develop a research handbook that will set out the substantive details of controlled field testing and review procedures.

The relationship of federal agencies to Institutional Biosafety Committees. Dr. Jones mentioned that a recent GAO report concluded that the relationship between biosafety committees and federal agencies involved in reviewing proposals for the use of genetically engineered organisms is not well defined. A major goal of this Committee is to try to clarify, or help the Department to clarify the relationship between the national level and the Institutional Biosafety Committees. Any comments, options or possible initiatives that the Committee members and alternates might have would be appreciated.

At the conclusion of Dr. Jones' presentation, Dr. Osburn summarized the major things that took place during the meeting. He said in order to accomplish some of the responsibilities referred to in the meeting, he would appoint three working groups to look at research guidelines, review definitions to be included in the research guidelines, and to address levels of biocontainment for environmental releases. The initial working group assignments were as follows:

Guidelines working group: Dr. Anne Vidaver, Chair; Dr. Harold Hafs; Dr. John Gorham; Dr. Frank Whitmore; Mr. Jeffrey Gibbs; and Ms. Anne Hollander.

Definitions working group: Dr. Ed Korwek, Chair; Dr. John Kemp; Dr. Lois Miller; and Dr. Tom Wagner.

Biocontainment for environmental release working group: Dr. Richard Witter, Chair; Dr. Nicholas Frey; Dr. Linda Phaire-Washington; and Dr. Steven Lindow.

Plans for Next Meeting

The agenda for the next ABRAC meeting will include adoption of minutes, adoption of committee procedures, review of research guidelines, and comments from the different working groups.

Adjournment

The meeting was adjourned at 12:45 p.m., Thursday, March 24, 1988.

ALVIN L. YOUNG
Executive Secretary

BENNIE I. OSBURN
Chairperson, ABRAC

AGENDA

AGRICULTURAL BIOTECHNOLOGY RESEARCH ADVISORY COMMITTEE (ABRAC)

March 23-24, 1988
9:00 a.m. - 5:00 p.m.
Jefferson Auditorium
USDA South Building
14th and Independence Avenue, S.W.
Washington, D.C.

FIRST DAY - MARCH 23, 1988 – Note: Times are approximate.

9:00 a.m.	Welcome Charge to the Committee Introduction of Chairman	Dr. Orville G. Bentley, Assistant Secretary Science and Education
9:20	Call to Order Introduction of Members and Office of Agricultural Biotechnology (OAB) Staff	Dr. Bennie I. Osburn, Chairman, Agricultural Biotechnology Research Advisory Committee
10:30	Welcome	Honorable Peter C. Myers Deputy Secretary United States Department of Agriculture
10:40	Break	
11:00	Comments	Dr. Kenneth A. Gilles Assistant Secretary Marketing and Inspection Services

AGENCY PRESENTATIONS

11:15	Agricultural Research Service	Dr. Jerome P. Miksche National Program Leader Plant Physiology
12:15	LUNCH	
1:30 p.m.	Forest Service	Dr. Stanley L. Krugman Director, Timber Management Research U.S. Forest Service
2:00	Cooperative State Reearch Service	Dr. John Patrick Jordan Administrator Cooperative State Research Service
2:50	Break	

3:05	**Economic Research Service**	**Dr. John E. Lee** **Administrator** **Economic Research Service**
3:30	**Animal and Plant Health Inspection Service**	**Terry L. Medley, Esq.** **Director, Biotechnology and Evironmental Coordination Staff** **Animal and Plant Health Inspection Service**
4:30	**Food Safety and Inspection Service**	**Dr. Lester M. Crawford** **Administrator** **Food Safety and Inspection Service**
5:00	**Adjourn**	

6:30 - 8:00 **ABRAC RECEPTION** *(By Invitation Only)*

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Capitol Holiday Inn
Columbia Room North
550 C Street, S.W.
Washington, D.C.

SECOND DAY – MARCH 24, 1988

9:00 a.m.	**Call to Order**	**Dr. Bennie I. Osburn**
	Purpose and Role of Committee	**Dr. Alvin L. Young**
	Administrative Matters	**Ms. Eva Russnak**
	Committee Operational Matters	Dr. Osburn, ABRAC Committee, OAB Staff

1. Frequency of Meetings
2. Development of Agendas
3. Announcement of Meetings
4. Attendance and Participation by Alternates
5. Pre-meeting Informational Materials
6. Rules of Order
7. Voting
8. Ad hoc Committees
9. Primary Reviewers
10. Priority Order of Speaking
11. Conflicts of Interest and Appearances of Conflict
12. Recording of Meetings
13. Preparation of Minutes
14. Confidential Business Information
15. Closed Sessions
16. Adjournment Authorities
17. Public Information

Preview of Upcoming Issues — Dr. Daniel Jones

Pending NIH Actions

Agricultural Research Guidelines
Federal Register Publication
Biotechnology Research Handbook

Federal Relationship with Institutional Biosafety Committees

ADJOURNMENT

APPENDIX B

DRAFT

OFFICE OF AGRICULTURAL BIOTECHNOLOGY (OAB)

RECOMMENDATIONS CONCERNING OPERATIONAL MATTERS FOR THE

AGRICULTURAL BIOTECHNOLOGY RESEARCH ADVISORY COMMITTEE (ABRAC)

1. Frequency of Meetings

OAB Recommendation: ABRAC meetings will be held at approximately quarterly intervals, i.e., every three months, unless Committee business warrants a change in frequency. Meetings are held at the call of the Chair. The Executive Secretary may recommend specific dates for meetings. Proposed dates for the next three meetings are June 23-24, 1988, September 22-23, 1988, and January 5-6, 1989.

2. Development of Agendas

OAB Recommendation: OAB will develop agendas for ABRAC meetings in consultation with the ABRAC Chair. Members or alternates may recommend agenda items to the Chair or Executive Secretary. Notice of major actions on the ABRAC agenda will be published in the Federal Register at least 30 days before the meeting at which they are discussed. Members of the public may submit written comments to the Chair or Executive Secretary in response to the Federal Register notice.

3. Announcements of Meetings

OAB Recommendation: OAB will prepare announcements of meetings for publication in the Federal Register at least 30 days prior to the meeting. Shorter notice may be provided in special situations if the reasons for the special exception are made part of the meeting notice.

4. Attendance and participation by alternates

OAB Recommendation: Members will ordinarily attend meetings, exercise voting privileges, and receive reimbursement for their services. If a member is unable to attend a particular meeting, his or her alternate may attend the meeting in place of the member. Alternates may exercise voting privileges and receive reimbursement only if they are substituting for a member at a particular meeting.

5. Pre-meeting informational materials

OAB Recommendation: OAB will distribute pre-meeting informational materials to both members and alternates in as timely a manner as possible. Multiple mailings may be necessary in some instances.

6. Rules of order

OAB Recommendation: Standard rules of order such as Robert's Rules of Order may be used at the Chair's discretion. Departures from such standard rules of order may be made at the Chair's discretion.

7. Voting

OAB Recommendation: Only members, including the Chair, and alternates substituting for members at a particular meeting may vote on issues before the Committee. The Executive Secretary will perform a quorum check at the beginning of each meeting to verify that at least 7 members are present and to determine which alternates are entitled to vote at that particular meeting.

The Executive Secretary or his/her designee will be responsible for counting hand votes and recording them. For each issue on which a vote is taken, the minutes will show the number of votes for, votes against, and abstentions. If members so request, the minutes will identify them by name as members who cast votes for or against a particular issue. Members may submit minority opinions for inclusion in the minutes.

8. Primary reviewers

OAB Recommendation: If an issue or proposal before the Committee requires expertise that is present on the Committee, the Chair will designate a primary reviewer or reviewers from the Committee members. Primary reviewers will be responsible for reviewing assigned material and reporting the results of the review to the full Committee, usually at a subsequent meeting.

9. Mailout reviewers

OAB Recommendation: If an issue or proposal before the Committee requires expertise that is not present among the Committee membership, OAB will, with the assistance of the National Biological Impact Assessment Program (NBIAP) or other resources, identify appropriate outside reviewers. OAB will mail out the material to be reviewed to the outside reviewers individually, receive the written reviews from the outside reviewers individually, and assemble the reviews for subsequent ABRAC review. Outside reviewers will not communicate with each other concerning the information under review or other items of ABRAC business. Review packages submitted to the ABRAC will identify the persons who developed the individual reviews.

10. Working Groups

OAB Recommendation: The Chair may appoint working groups from among ABRAC members to address specific questions between ABRAC meetings. The OAB Director will furnish the information to be reviewed to the working group members and their corresponding alternates. Working group alternates may communicate with the member for whom they are the alternate concerning the information under review, but they will not communicate with other alternates concerning the information under review or other items of ABRAC business. Alternates may also communicate directly with the Director, OAB.

11. Priority order of speaking

OAB Recommendation: The Chair will determine the priority order of speaking on specific issues. OAB recommends the following generic order of speaking: 1) primary reviewers, 2) mailout reviewers who may be present, 3) other Committee members or alternates substituting for members, 4) OAB staff, 5) alternates present but not substituting for members or serving as primary reviewers, 6) agency, committee, or organization liaisons to ABRAC identified in OAB records, 7) members of the audience who have submitted written comments, and 8) members of the general audience. The Chair may limit the time available to any speaker before the Committee.

12. Conflicts of interest and appearances of conflict

OAB Recommendation: Committee members and alternates are expected to use discretion in avoiding conflicts of interest and the appearance of conflict in their Committee activities. Avoidance measures include absenting themselves from Committee discussions on specific subjects and abstention from voting as appropriate. The Executive Secretary may advise members or alternates on conflict-related concerns.

13. Recording of meetings

OAB Recommendation: All open ABRAC meetings will be recorded and a written transcript prepared by a commercial recording service.

14. Preparation of minutes

OAB Recommendation: The Executive Secretary or his/her designee will prepare draft minutes of ABRAC meetings from the written transcript. Minutes will be amended or approved by the full Committee, certified by the Chair, and signed by the Executive Secretary or his/her designee.

15. Public information

OAB Recommendation: ABRAC members and alternates are encouraged to cooperate as fully as possible with representatives of the media. When the ABRAC is in session, the Chair will normally serve as the ABRAC spokesperson. In his absence, the Executive Secretary or his designee will serve as media spokesperson. ABRAC members and alternates may give interviews as requested if they wish. OAB requests that the OAB public affairs specialist be notified of such interviews in a timely fashion. ABRAC members and alternates may not at any time discuss confidential business information with anyone outside the Committee including media representatives.

16. Confidential business information

OAB Recommendation: OAB is preparing a proposed rule on confidential business information for publication in the Federal Register. Committee members and alternates will receive copies of the proposal after it has been signed by the Deputy Secretary. Committee members and alternates will be required to sign appropriate commitment and receipt forms before they can receive confidential business information in connection with official Committee business.

17. Closed sessions

OAB Recommendation: For a meeting or part of a meeting at which confidential business information is discussed, OAB will prepare a notice for publication in the Federal Register which announces a closed session and gives the reasons for closing the session.

18. Adjournment authorities

OAB Recommendation: Ordinarily, the Chair or his/her designee will adjourn meetings. However, if the Chair is a non-federal employee, the Executive Secretary shall have the authority and be required to adjourn any meeting under circumstances in which he/she considers adjournment to be in the public interest.

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